DEPARTMENT OF HEALTH AND HUMAN SERVICES

**AGENCY: Office of the Assistant Secretary for Health, Office of Population Affairs** 

FUNDING OPPORTUNITY TITLE: Announcement of Availability of Funds for Embryo

Adoption/Donation Services and Public Awareness Grants.

**ACTION: Notice** 

**ANNOUNCEMENT TYPE: Initial Competitive Grant** 

**FUNDING OPPORTUNITY NUMBER: PA-EAA-19-001** 

**CFDA NUMBER: 93.007** 

CFDA PROGRAM: Public Awareness Campaigns on Embryo Adoption

**DATES:** 

**Technical Assistance:** 

A technical assistance webinar for potential applicants will be held between two and four weeks

from the release of the announcement on Grants.gov. Please check HHS.gov/opa for more

information.

We recommend you review the entire announcement promptly so you can have any

questions answered well in advance of the application due date. We also recommend you

subscribe to this announcement in Grants.gov so you receive any amendments, question

and answer documents, or other updates.

Applications: Your application is due May 20, 2019 by 6 p.m. Eastern Time. To receive

consideration, you must submit your application electronically via Grants.gov no later than this

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due date and time. If you do not submit your application by the specified deadline, we will return it to you unread. You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, HHS/Office of the Assistant Secretary for Health (OASH) Office of Grants Management (OGM). To obtain an exemption, you must request one via email from the HHS/OASH OGM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline. If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's DUNS number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (for example, GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to <a href="mailto:ogm.oash@hhs.gov">ogm.oash@hhs.gov</a>. Note: failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will <u>not</u> be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH OGM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an

approved written exemption will be accepted. *See* Section D.7 ("Other Submission Requirements") for information on application submission mechanisms.

Executive Order 12372 comment due date: The State Single Point of Contact (SPOC) has 60 days from the application due date to submit any comments. For more information on the SPOC see section D.4 Intergovernmental Review.

To ensure adequate time to submit your application successfully, HHS/OASH recommends that you register as early as possible in Grants.gov since the registration process can take up to one month. You must register an authorizing official for your organization. HHS/OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to <a href="http://www.grants.gov">http://www.grants.gov</a> or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or <a href="mailto:support@grants.gov">support@grants.gov</a>.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

EXECUTIVE SUMMARY: The Office of Population Affairs (OPA) announces the availability of funds for Fiscal Year (FY) 2019 grant awards under the authority of Division B, Title II of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and Section 1704 of the Public Health Service Act (42 U.S.C. § 300 u-3). This notice solicits applications for projects which propose interventions that improve upon and/or expand services related to embryo adoption/donation, and/or which increase public awareness of embryo

adoption/donation as a method of family building. OPA anticipates funding 3-5 grants in the range of \$100,000-\$300,000 per grant per year. Approximately \$700,000 will be awarded through this funding opportunity in fiscal year 2019 and a similar amount in fiscal year 2020 (dependent on the availability of funding). Non-profit as well as for-profit organizations are eligible for this funding. Organizations, but not individuals, are eligible for this funding. Costsharing is not required.

HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that its application complies with all requirements and instructions.

### A. PROGRAM DESCRIPTION:

The Embryo Adoption Public Awareness Campaign was first funded by Congress in fiscal year 2002. The original purpose of the program was to increase public awareness of the existence of a large number of human embryos remaining after *in vitro* fertilization procedures, some of which might be available for adoption by infertile couples. In fiscal year 2008, Congress expanded the scope of the program to include interventions that provided "medical and administrative services" to individuals and couples in order to facilitate the adoption and donation of embryos for the purpose of family formation.

The National Survey of Family Growth (NSFG) has collected information over the past several years regarding the behaviors and access to health services of females and males within the United States of America related to family formation and reproductive health. Data from the 2012 NSFG release (which received partial support from the Embryo Adoption Awareness

program) suggested that nearly two-thirds of U.S. women of reproductive age knew of embryo adoption/donation as a method of family formation. Preliminary analysis from more recent studies indicate that awareness continues to increase. Building upon the public's awareness, in 2016, OPA supported a small but in-depth study of obstetrician/gynecologists' knowledge and practices regarding embryo adoption/donation. Though awareness of embryo adoption/donation was nearly universal among the study participants, none of them had ever offered education and counseling on embryo adoption/donation nor suggested it to a patient.

This funding opportunity will build upon previous efforts and focus on interventions that develop and/or provide innovative services (including education and counseling) that facilitate the use of embryo adoption/donation as a method of family formation. Recipients of the services, undertaken as part of the proposed projects, should be individuals that are currently involved, soon may be involved, or are interested in adopting or donating remaining embryos. This may include individuals that are infertile, experiencing difficulty achieving a pregnancy, interested in having more children through frozen embryo transfer, or have surplus embryos. Applications may propose new ideas or they may identify existing projects to modify, augment or attempt to bring to scale interventions which have a high likelihood of improving access to, facilitating, or reducing barriers to embryo adoption/donation. For this reason, applicant organizations are permitted to apply for up to a two-year project period. The expectation is that successful applications will have a plan and strategy to continue the project beyond the project period.

HHS/OASH and OPA are interested in projects which address a variety of "medical" and "administrative services" that facilitate the use of embryo adoption/donation as a method of

family formation. For the purposes of this announcement, education and counseling are considered "medical services." "Administrative services" are those that address and help embryo adoption/donation patients to negotiate the process of embryo adoption/donation, and to overcome the financial, legal and other non-biologic obstacles that may occur in the process of embryo adoption/donation. Training of professionals to enable them to provide administrative and/or medical services to facilitate embryo adoption and donation is also included within this aspect of the program. Applicants may also propose projects that improve the knowledge and awareness of embryo adoption and donation for individuals that are interested or may be interested in this method of family formation, in the form of targeted public awareness campaigns. Additionally, projects may propose to include a combination of the medical services, administrative services and/or public awareness aspects described above in a single application. Successful applications will provide detailed descriptions of innovative approaches to improve, at a minimum, the likelihood of individuals and couples to consider adopting embryos and/or donating their unused embryos. In the narrative section of the application, applicants should clearly describe the strategies and processes that they will use to design, implement, and assess their proposed project. It is critical that applicants clearly describe how they will measure success, including but not limited to establishing quantifiable targets and attainable goals. Applicants should clearly identify the process and reason for identifying the individuals that will receive the services (i.e., medical and/or administrative) and/or the target audience(s) of the campaign(s) that focus on increasing the knowledge, awareness, and ability to access embryo adoption and/or donation services. It is highly recommended that the proposed project incorporate current, evidence-based information in all phases of the design, delivery, and evaluation. Applicant organizations should demonstrate competency in the design, development, implementation; the ability to successfully complete the proposed project; and capacity to assess the outcomes of all activities. The successful applicant will provide evidence of familiarity with embryo donation and/or adoption and the ability to translate evidence-based information into the proposed activities. A detailed plan and strategy for how the outcomes of the project will be used beyond the requested funding period should also be included.

Applicants are also encouraged to devise strategies to identify the various professional audiences associated with embryo donation and/or adoption and to develop interventions that involve professionals (e.g., gynecologists and other reproductive medicine physicians, nurses, embryologists, family practice lawyers, adoption counselors, ethicists, social workers, IVF clinic staff, embryo storage facility staff, etc.) associated with the legal, medical, psycho-social, ethical and practical issues associated with both embryo donors and embryo recipients.

For applications that are proposing projects to address medical and/or administrative services that facilitate the use of embryo adoption/donation as a method of family formation:

Successful applicants will clearly and fully explain their strategies on how they will deliver services that increase the ability of individuals or couples to donate or adopt frozen embryos.

Strategies aimed at increasing the percentage of currently frozen embryos that are made available for donation/adoption are acceptable under this program. Additionally, projects that propose services to assist individuals in determining the number of embryos to be created, as well as, education and counseling and education around options to consider if surplus embryos remain once it is determined that the use in one's own family formation has been completed, are also acceptable under this program.

If proposing projects to provide education and counseling and education and related medical services, applicants should consider including approaches that inform individuals that are infertile or experiencing difficulty achieving a pregnancy about the option of considering embryo donation/adoption at the same time they are receiving education and counseling on other options including, but not limited to infertility treatments and other assisted reproductive technologies (ART).

Training professionals to offer medical or administrative services to individuals and couples who are involved in embryo donation/adoption is included in the "services" aspect of the program. Applicants may conduct training activities for professionals that offer individuals or couples help with the medical, legal, psycho-social, ethical, and practical issues surrounding embryo donation and/or adoption. These types of trainings should be designed to enhance the ability of multiple levels of providers to share information and to assist potential donors with embryo donation and/or adoption. Training design and content should be adjusted to the skill and practice role of the target audience. Appropriate continuing education credits may be made available for professional training activities provided under this announcement. The content and number of offerings should be based on an assessment of the need. These offerings should be designed and delivered in a manner appropriate to the content of the course as well as professional preparation of the participants.

For applications that are proposing projects to increase the knowledge and awareness of embryo adoption and donation for individuals that are interested or may be interested in this method of family formation, in the form of targeted public awareness campaigns:

Successful applicants will clearly document their capacity to undertake a campaign focused on the specific audience(s) they are directing their project toward. The narrative should address why the need to target the audience(s) exists and how the campaign will bring greater awareness, understanding, and potentially increase the likelihood of receiving donated embryos for family formation or making more embryos available for adoption/donation. Campaigns should be directed at specific populations, including, but not limited to individuals likely to donate and/or accept donated embryos for family formation or medical and other professionals that provide medical or administrative services related to the treatment of infertility, ART, and related fields. Services provided by applicant organizations must be offered consistent with 42 CFR 59.5(a)(4), which requires that services be provided "without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status." Project funds cannot be used to pay for human tissues, nor for any approach that may be construed as involving compensation for the donation of human tissues. Reimbursement of an embryo donor's already accrued costs, including but not limited to storage fees, is not considered an acceptable practice in this program.

**AUTHORITY:** This program is authorized by Division B, Title II of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and Section 1704 of the Public Health Service Act (42 U.S.C. §300 u-3).

### B. FEDERAL AWARD INFORMATION

OPA intends to make funds available for competing grants.

We will fund awards in annual increments (budget periods) and generally for a project period up to two years, although we may approve shorter project periods. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

Award Information

Estimated Federal Funds Available: \$700,000

Anticipated Number of Awards: 3-5

Award Ceiling (Federal Funds including indirect costs): \$300,000per budget period

Award Floor (Federal Funds including indirect costs): \$100,000 per budget period

Anticipated Start Date: 07/01/2019

Estimated Period of Performance: Not to exceed 2 years

Anticipated Initial Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov ONLY unless an exemption is

granted

### C. ELIGIBILITY INFORMATION

1. Eligible Applicants. Only agencies and organizations, not individuals, are eligible to apply. Eligible applicants include public agencies, non-profit organizations, or for-profit organizations. Educational institutions—including colleges, universities, academic medical centers and/or their affiliated clinics—are eligible to apply for this grant. Faith-based organizations and American

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Indian/Alaskan Native/Native American (AI/AN/NA) organizations are also eligible to apply. Multiple organizations may apply together, however, one agency must be identified as the applicant organization and this agency will have legal responsibility for the project. These additional agencies and organizations can be included as co-participants, subgrantees, subcontractors, or collaborators if they assist in providing expertise and in helping to meet the needs of the recipients.

- 2. Cost Sharing or Matching You are not required to provide cost sharing or matching in your proposed budget.
- 3. Other Eligibility Information

## **Application Disqualification Criteria**

If you successfully submit an application, we will screen it to ensure it meets the below requirements. If we determine your application fails to meet the criteria described below we will disqualify it, that is, we will **not** review it and will give it **no** further consideration.

- a) You must submit your application electronically via <a href="www.grants.gov">www.grants.gov</a> (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section of this announcement.
- b) If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.
- c) HHS/OASH/OGM deems your application eligible according to section C.1 *Eligible Applicants*.
- d) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.

e) Your Project Narrative section of the application must be double-spaced, on the equivalent of

8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font

size not less than 12 points.

f) Your Project Narrative must **not** exceed 40 pages. NOTE: The following items do not count

toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-

424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).

g) Your total application, including the Project Narrative plus Appendices, must **not** exceed 65

pages. NOTE: items listed in "e" immediately above do not count toward total page limit.

h) Your Federal funds request including indirect costs must **not** exceed the maximum indicated

in Award Ceiling.

i) Your Federal funds request including indirect costs must **not** be below the minimum

indicated in Award Floor.

D. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at

http://www.grants.gov/. You can find it by searching on the CFDA number shown on page 1 of

this funding opportunity announcement. If you have problems accessing the application or

difficulty downloading, contact:

Office of Grants Management

Phone: 240-453-8822

Email: ogm.oash@hhs.gov

2. Content and Form of Application Submission

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# i. Application Format

Your application must be prepared using the forms and information provided in the online application package.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria. Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices when printed on 8.5" X 11" paper by HHS/OASH/OGM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

### You must double-space the Project Narrative pages.

You should use an easily readable typeface, such as Times New Roman or Arial. You *must* use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

## **Appendices Format**

Your Appendices should include any specific documents outlined in Section D.2.iii., under the heading "Appendices" in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the

pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

# Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

# **Budget Narrative Format**

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

## ii. Application Content

Successful applications will contain the following information:

## **Project Narrative Content**

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

- 1) Project Summary: Provide a summary of the project not to exceed one page. Care should be taken to produce a summary that accurately and concisely reflects the proposed project, especially in regard to the project's major goals and objectives. This summary will be used to provide reviewers with an overview of the application. The summary should describe the objectives of the project, the approach to be used and the results or benefits expected. This project summary may be posted on the OPA website if the project is awarded a grant.
- 2) Need for Assistance: Demonstrate a clear understanding of the program goals and explain how the particular approach will contribute to achieving these goals. Clearly identify the clinical/healthcare, physical, economic, social, legal, financial, institutional, and/or other problem(s) requiring a solution. Clearly describe and provide a justification for selecting the specific populations and/or groups to participate in the activities proposed within the application. Note that grant funds may only be used for domestic purposes and activities. Describe the rationale for use of the proposed approach based upon previous practice, review of the literature, and evaluation findings. Any relevant data based on studies should be included or referred to in the proposed approach and referred to in the endnotes/footnotes.
- 3) Approach and Objectives: The applicant should provide a detailed work plan and timetable as well as goals and objectives that are specific, measurable, achievable, realistic and time-framed (SMART) for the proposed project. Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions and activities identified in the application. Cite factors that might accelerate or decelerate the work, and state reasons for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and/or community involvement. Provide quantitative monthly or quarterly

projections of the accomplishments to be achieved for each function or activity in such terms as the number of program activities to be held, or appropriate measurable outcomes. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of the accomplishments and their target dates.

4) Evaluation: Provide a detailed narrative addressing how results of the project and conduct of the project will be evaluated. In addressing the evaluation of results, the successful applicant will determine the extent to which the project has achieved its stated objectives and the extent to which this accomplishment of objectives can be attributed to the action of the project. The evaluation should be based on a model or approach that links the program interventions to the program's objectives. The applicant should discuss the criteria used to evaluate results, and explain the methodology that will be used to decide if the identified needs are being met and if the project results are being achieved. Applicants that do not have the in-house capacity to conduct an evaluation are advised to propose contracting with a third-party evaluator to conduct the evaluation.

With respect to the conduct of the project, the applicant should define the procedures to be employed and should discuss the impact of the project's various activities on the project's effectiveness.

5) Organizational Profiles: Provide information on the applicant organization and cooperating partners such as organizational charts, documentation of professional accreditation, documentation of experience in the program area, and other pertinent information. Applicants should demonstrate an understanding of the intended audience as well as the information and skills needed by the designated staff. Applicants are advised to show that they have the organizational capacity and resources to carry out the project on time and to a high standard of

quality, including the capacity to resolve a variety of technical and management problems that may occur. Capacity includes, but is not limited to: 1. Previous experience with similar projects; 2. Experience with the target audience; 3. Qualifications and experience of the project leadership, including those who are consultants or subcontractors; and, 4. Suitability of the organizational structure for the proposed project. Applicants are expected to present a feasible management plan for implementing the proposed program. This section should detail how the program will be structured and managed, how timeliness of activities will be ensured, how quality will be maintained, and how costs will be controlled. If applicable, the role and responsibilities of the lead agency should be clearly defined and applicants should describe the management and coordination of activities carried out by any partners, subcontractors, or consultants.

## **Budget Narrative**

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF 424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance).

Please be sure to carefully review section D.6 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF 424A for the first year of the proposed project. Provide a budget justification, which includes explanatory text and line-item detail, for the first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not** include costs beyond the first budget year in the object class budget in box 6 of the SF- 424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget year.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (when required) must be detailed and justified in the budget narrative. "Federal resources" refers only to the

HHS/OASH funds for which you are applying. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

## Sample Budget Table

Object Class	Federal Funds	Non-federal	Total Budget
	Requested	Resources	
Personnel	\$100,000	\$25,000	\$125,000

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel.

Object Class Descriptions and Required Justifications

Personnel Description: Costs of staff salaries and wages, excluding benefits.

Personnel Justification: Clearly identify the project director or principal investigator, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see D.6 Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. Contractors and consultants should not be placed under this category.

Sample Personnel Table

Position Title	Percent Time	Annual Salary	Federally-	Non-	Total
and Full Name			funded Salary	federal	Project
				Salary	Salary
Project	50%	\$100,000	\$50,000	\$0	\$50,000
Director, John					
K. Doe					
Data Assistant,	10%	\$30,000		\$3,000	\$3,000
Susan R.					
Smith					

Fringe Benefits Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

Fringe Benefits Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

Travel Description: Costs of travel by staff of the applicant organization only.

Travel Justification: For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors.

Equipment Description: "Equipment" means an article of nonexpendable, tangible personal property having a useful life of more than one year per unit and an acquisition cost that equals or exceeds the lesser of: (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories,

or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired.

Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation, shall be included in or excluded from acquisition cost in accordance with your organization's regular written accounting practices.)

Equipment Justification: For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

Supplies Description: Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a perunit cost of less than \$5,000.

Supplies Justification: Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

Contractual Description: Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. This line item is not for individual consultants.

Contractual Justification: Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 CFR § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134, as described in 2 CFR § 200.88, and currently set at \$250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Note: Whenever you intend to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each subrecipient/contractor, by agency title, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, the applicant must provide information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency.

Other Description: Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

Other Justification: Provide computations, a narrative description, and a justification for each cost under this category.

Indirect Costs Description: Total amount of indirect costs. This category has one of two methods that an applicant may select. You may only select one.

- 1) Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.
- 2) Per 45 CFR § 75.414(f) Indirect (F&A) costs, "any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, ... may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time."

This method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Indirect Costs Justification: Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved

agreement is being applied and why that rate is being used. For example, if you have both oncampus and off-campus rates, identify which is being used and why.

Program Income Description: Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 CFR § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 CFR §§ 75.307, 75.407 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

Program Income Justification: Describe and estimate the sources and amounts of Program Income that this project may generate if funded. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. This amount should be reflected in box 7 of the SF-424A.

Non-Federal Resources Description: Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 CFR § 75.306. For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by project period for fully-funded awards, even if the justification by budget period, or by project period for fully-

funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. Note, you will not receive any preference, priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

Non-federal Resources Justification: You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding (\$)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by project period for fully-funded awards).

If your application does not include the required supporting documentation, it will not be disqualified from competitive review; however, it may impact your score under the evaluation criteria in Section V.1 of this announcement.

Plan for Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities
  and partner(s) will adhere to applicable federal award and programmatic regulations.
   Include identification of risks specific to your project as proposed and how your
  oversight plan addresses these risks.
- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- o for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal
   Financial Reports to the OASH Office of Grants Management and Payment Management
   Services as well as timely and appropriate withdrawal of cash from the Payment
   Management System.

# **Appendices**

All items described in this section will count toward the <u>total</u> page limit of your application. You must submit them as a single electronic file uploaded to the Attachments section of your Grants.gov application.

#### Work Plan

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the project period. You may propose multi-year activities, as well as activities that build upon each other. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task.

## **Letters of Commitment from Subrecipient Organizations and Agencies**

You should include signed Letters of Commitment for all organizations and entities that have been specifically named as a subrecipient to carry out any aspect of the project. The signed letters of commitment *must detail* the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment.

Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support, and letters of support such as this will not be considered during the review.

### Curriculum Vitae/Résumé for Key Project Personnel

You must submit with your application curriculum vitae and/or résumés of the Project Director/Principal Investigator and all other Key Personnel. Key Personnel includes those

individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum Program Manager/Program Coordinator. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records.

# 3. <u>Unique Entity Identifier and System for Award Management (SAM)</u>

- You are required to provide a Dun and Bradstreet (D&B) Data Universal
   Numbering System (DUNS) number when applying for Federal awards through
   Grants.gov. It is a unique, nine-digit identification number, which provides
   unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- You will find instructions on the Grants.Gov web site as part of the organization registration process at <a href="http://www.grants.gov/web/grants/applicants/organization-registration.html">http://www.grants.gov/web/grants/applicants/organization-registration.html</a>.
- Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations.
- If you are registering a <u>new</u> entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to <u>SAM.GOV</u> For detailed instructions on the content of the letter and process for domestic entities see: <a href="https://www.fsd.gov/fsd-">https://www.fsd.gov/fsd-</a>

gov/answer.do?sysparm\_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm\_search=kb0013183

- A quick start guide for registrants is available at <a href="https://www.sam.gov/sam/transcript/Quick Guide for Grants Registrations.pdf">https://www.sam.gov/sam/transcript/Quick Guide for Grants Registrations.pdf</a>. You should allow a *minimum* of five days to complete an initial SAM registration. Allow up to 10 business days *after you submit* your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.
- If your organization is already registered in SAM, you must renew your SAM registration *each* year. Organizations registered to apply for Federal awards through <a href="http://www.grants.gov">http://www.grants.gov</a> will need to *renew* their registration in SAM.
- You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4.

  Should you successfully compete and receive an award, this information must be included on a Notice of Award. For instructions on updating this information see <a href="https://gsafsd.service-now.com/fsd-gov/answer.do?sysparm\_kbid=c3d982af6fb8d5006f348d412e3ee47e">https://gsafsd.service-now.com/fsd-gov/answer.do?sysparm\_kbid=c3d982af6fb8d5006f348d412e3ee47e</a>
- It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.
- If you are successful and receive an award, you must maintain an active SAM
   registration with current information at all times during which your organization

has an active award or an application or plan under consideration by an HHS agency.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 CFR § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

- May determine that you are not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.
   Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number at the time you, the recipient, make a sub-award.

## 4. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in the DATES section of this announcement.** Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your submission.

If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <a href="http://www.grants.gov">http://www.grants.gov</a>. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the

time of your submission and that time was before the submission deadline. A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.

# 5. <u>Intergovernmental Review</u>

Applications under this announcement are subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented by 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." As soon as possible, you should discuss the project with the State Single Point of Contact (SPOC) for the State in which your organization is located. The current listing of the SPOCs is available at <a href="https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-2018.pdf">https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-2018.pdf</a>.

The SPOC should forward any comments to the Department of Health and Human Services 1101 Wootton Parkway, Suite 550, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH Office of Grants Management at 240–453–8822.

## 6. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 CFR part 75 "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards," Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 CFR § 75.414. See the Budget Narrative section of this announcement for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at https://rates.psc.gov/fms/dca/map1.html.

Pre-Award Costs:

Pre-award costs are not allowed.

## Salary Rate Limitation:

Each year's appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 7, 2018, the Executive Level II salary is \$189,600. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's <i>actual</i> base full time salary: \$350,000		
50% of time devoted to project, i.e5 FTE		
Direct salary (\$350,000 x .5)	\$175,000	
Fringe (25% of salary)	\$43,750	
Total	\$218,750	

Amount that may be claimed on the application budget due to the legislative salary rate limitation:			
Individual's base full time salar	ry adjusted to Executive Level II: \$189,600 with		
50% of time devoted to the proj	ject		
Direct salary (\$189,600 x .5)	\$94,800		
Fringe (25% of salary)	\$23,700		
Total amount allowed	\$118,500		

Appropriate salary rate limits will apply as required by law.

## 7. Other Submission Requirements

Electronic Submission

HHS/OASH requires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it will not be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at <a href="http://www.grants.gov">http://www.grants.gov</a>.

Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF,

Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file

format extension in the filename. HHS/OASH strongly recommends that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission you may prevent any unintentional formatting that might occur with submission of an editable document. Please note, even though Grants.gov allows you to attach any file format as part of your application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files.

Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files.

Compressed information in the application will not be forwarded for consideration.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

# **Important Grants.gov Information**

You may access the electronic application for this program on http://www.grants.gov.

You must search the downloadable application page by the Funding Opportunity Number or

CFDA number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions provided at <a href="http://www.grants.gov/web/grants/applicants/apply-for-grants.html">http://www.grants.gov/web/grants/applicants/apply-for-grants.html</a>. These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Contacts below. See Section D.3 for requirements related to DUNS numbers and SAM registration.

### E. APPLICATION REVIEW INFORMATION

1. <u>Criteria:</u> Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria

Criterion 1: Need for Assistance (35 Points)

- (1) The extent to which the application reflects an understanding of the goals of the embryo adoption program, and how implementation will contribute to achieving these goals;
- (2) The extent to which the application accurately describes the need for assistance to: a) make services "medical" and "administrative" as described in the FOA, , available to

people that are currently involved (or may soon be involved in) the process of embryo adoption/donation; or (b) increase public awareness of embryo adoption/donation;

- (3) The extent to which the application explains how the proposed project will contribute to increased knowledge of the problems, issues, and effective strategies and best practices in the field of embryo adoption/donation; and
- (4) The extent to which the applicant discusses the broad contextual factors that will facilitate or impede the project.

Criterion 2: Approach and Objectives (30 Points)

- (A) Design of the Project:
- (1) The extent to which the application reflects an understanding of relevant Federal or State laws and regulations pertaining to embryo adoption/donation,
- (2) The extent to which the proposed project goals, objectives, and outcomes are clearly specified and measurable, and
- (3) The extent to which the intended audience is clearly identified and defined and is appropriate to the goals of the proposed project;
- (B) Implementation of the Project:
- (1) The extent to which the application presents an appropriate, feasible, and realistic plan for conducting the project;

(2) The extent to which the proposed project will establish and coordinate linkages with

other appropriate agencies and organizations.

(C) Dissemination of the Project:

(1) The extent to which the products being developed during the project are described

clearly and will address the goal of dissemination of information and are designed to

support evidence-based improvements of practices in the field of embryo

adoption/donation.

Criterion 3: Evaluation (15 Points)

(1) The extent to which the methods of evaluation are feasible, comprehensive, and

appropriate to the goals, objectives, and context of the project, including but not limited to

measuring the effectiveness of the project; and

(2) The extent to which the methods of evaluation include process and outcome analyses,

as appropriate, for assessing the effectiveness of the program strategies and implementation

process.

Criterion 4: Organizational Profile (20 Points)

(A) Organizational Capacity and Resources - The extent to which the management plan

presents a realistic approach to achieve the objectives of the proposed project on time and

within budget, including clearly defined responsibilities, time lines and milestones for

accomplishing project tasks;

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(B) Staff Qualifications - The extent to which the proposed project director, key project staff, and consultants have the necessary technical skill, knowledge, and experience to carry out their responsibilities; and,

### (C) Management Plan:

- (1) The extent to which the fiscal controls and accounting procedures are in place to ensure timely and accurate reporting of grant expenditures, drawdowns and related financial transactions;
- (2) The extent to which prudent use, proper and timely disbursement, and an accurate accounting of funds received under this announcement are described.

#### 2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance. The Deputy Assistant Secretary for Population Affairs will provide recommendations for funding to the Grants Management Officer to conduct risk analysis.

### 3. Review of Risk Posed by Applicant

The HHS/OASH will evaluate, in accordance with 45 CFR § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. OASH will use a risk-based approach and may consider any items such as the following:

- (a) Your financial stability;
- (b) Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;
- (c) History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- (d) Reports and findings from audits performed; and
- (e) Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently \$250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If an we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 CFR §75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must "demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics." 45 CFR § 75.205(a)(2); see also 45 CFR §75.212 for additional information.

## **4. Final Award Decisions,** Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management

Officer, HHS/OASH will issue Notices of Award. No award decision is final until a Notice

of Award is issued. All award decisions, including level of funding if an award is made, are

final and you may not appeal.

HHS/OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B "Federal Award Information," as practicable, with a goal of 10-15 days.

Note this is an estimated start date and award announcements may be made at a later date and with a later project period start date.

#### F. FEDERAL AWARD ADMINISTRATION INFORMATION

## 1. Federal Award Notices

HHS/ OASH does not release information about individual applications during the review process. If you would like to track your application, please see instructions at <a href="http://www.grants.gov/web/grants/applicants/track-my-application.html">http://www.grants.gov/web/grants/applicants/track-my-application.html</a>. The official document notifying you that a project application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH OGM. If you are successful, you will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the project period, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by HHS/OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

# 2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, or other Department regulations and policies in effect at the time of the award.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at <a href="http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf">http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf</a> Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 CFR parts 74 and 92 have been superseded by 45 CFR part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section

II and 45 CFR § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

## Closeout of Award

Upon expiration of your project period, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be complete with your cooperation or that of the Principal Investigator/
Project Director, we may elect to complete a unilateral closeout. (See F.3 Reporting below for closeout reporting requirements.) As a result, we may determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

# **Lobbying Prohibitions**

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet,

publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

# Non-Discrimination Requirements

Pursuant to Federal civil rights laws, if you receive an award under this announcement you must not discriminate on the basis of race, color, national origin, disability, age, and in some

cases sex and religion. The HHS Office for Civil Rights provides guidance for complying with civil rights laws that prohibit discrimination. <a href="https://www.hhs.gov/civil-rights/index.html">https://www.hhs.gov/civil-rights/index.html</a>.

HHS provides guidance to recipients of federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency. See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311, 47313 (HHS Office for Civil Rights, 2003, <a href="https://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf">www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf</a>) You must ensure your contractors and subrecipients also comply with federal civil rights laws

The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, <a href="www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf">www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf</a>, provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency.

Compliance with the National CLAS Standards meets the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency.

#### Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

## Acknowledgement of Funding and HHS Rights to Materials and Data

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

This publication (journal article, etc.) was supported by Award No. \_\_\_\_\_\_ from the Office of the Assistant Secretary of Health (OASH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OASH.

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 CFR § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

## <u>Trafficking in Persons</u>

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104). For the full text of the award term, go to <a href="http://www.hhs.gov/opa/grants/trafficking\_in\_persons\_award\_condition.html">http://www.hhs.gov/opa/grants/trafficking\_in\_persons\_award\_condition.html</a>. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

## **Efficient Spending**

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at <a href="http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/">http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/</a>

#### Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 CFR § 3.908 to the award, and requires that you inform your employees <u>in writing</u> of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the <u>predominant native</u> <u>language</u> of the workforce.

### Same-sex Spouses, Marriages, and Households

A standard term and condition of award will be included in the final Notice of Award (NOA) that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary

eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions, or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage."

### **Human Subjects Protection**

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 CFR part 46. You may find it online at <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a>.

Applicants that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to <a href="https://www.hhs.gov/about-research-participation">www.hhs.gov/about-research-participation</a>.

## Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. Part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of Part 93 file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of Part 93. More information is available at ori.hhs.gov/assurance-program.

### 3. Reporting

#### Performance Reports

You must submit performance reports on a quarterly basis. Your performance reports must address content required by 45 CFR § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

You will also be required to submit a final performance report covering the entire project period 90 days after the end of the project period. You must submit the final report by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

Performance Measures At the end of each funding year of this initiative, you should be able to

Document the number of people receiving services because of project activities

Report on the progress made toward each of the documented measures identified as part

of your project plan.

Identify any barriers and obstacles encountered in the implementation of the project, including proposed or realized solutions to these challenges.

## **Financial Reports**

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire project period 90 days after the end of the project period. You must submit FFRs via our grants management system (GrantSolutions.gov) FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note, at this time, these FFR reports are separate submissions via the Payment Management System. At this time, data is not transferable between the two systems and you will report twice on certain data elements.

#### <u>Audits</u>

If your organization receives \$750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 45 CFR part 75, subpart F.

### Non-competing Continuation Applications and Awards

Each year of the approved project period, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. HHS/OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Additionally, failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

### FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<a href="http://www.FSRS.gov">http://www.FSRS.gov</a>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

### Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and

Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 CFR part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 CFR part 75.

## Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 CFR § 180.335, you as the participant must notify HHS/OASH, if you know that you or any of the principals for that covered transaction:

- (a) Are presently excluded or disqualified;
- (b) Have been convicted within the preceding three years of any of the offenses listed in 2 CFR § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- (c) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 CFR § 180.800(a); or
- (d) Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 CFR § 180.350, you

must give immediate written notice to HHS/OASH if you learn either that—

(a) You failed to disclose information earlier, as required by 2 CFR § 180.335; or

(b) Due to changed circumstances, you or any of the principals for the transaction now

meet any of the criteria in 2 CFR § 180.335.

**G. CONTACTS** 

Administrative and Budgetary Requirements:

For information related to administrative and budgetary requirements, contact the

HHS/OASH grants management specialist listed below.

Jessica Shields, Office of Grants Management

1101 Wootton Parkway, Suite 550

Rockville, MD

Phone: 240-453-8822

Email: Jessica.Shields@hhs.gov

**Program Requirements** 

For information on program requirements, please contact the program office representative listed

below.

Robert Scholle, Office of Population Affairs

1101 Wootton Parkway, Suite 700

Rockville, MD

Phone: 240-453-2848

Robert.Scholle@hhs.gov

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**Electronic Submission Requirements** 

For information or assistance on submitting your application electronically via Grants.gov,

please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

**GRANTS.GOV** Applicant Support

Website: www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

H. OTHER INFORMATION

Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If

awards are made, they may be issued for project periods shorter than indicated. Only the

grants officer can bind the Federal government to the expenditure of funds. If you receive

communications to negotiate an award or request additional or clarifying information, this does

not mean you will receive an award; it only means that your application is still under

consideration.

**Application Elements** 

The below is a summary listing of all the application elements required for this funding

opportunity

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Assurances for Non-construction Programs (SF-424B)

Disclosure of Lobbying Activities (SF-LLL)

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Project Abstract Summary

Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.

Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.

Appendices – Submit all appendix content as a single acceptable file, specified above in the Attachments section of your Grants.gov application.

Díane Foley	3/14/19	
Diane Foley, MD		
Deputy Assistant Secretary of Population Affairs	Date	